K100888

NOV 15 2010

510(k) SUMMARY

Lanx Posterior Cervicothoracic Spinal Fixation System

Submitter Information

Name and Address:	Lanx, Inc. 390 Interlocken Crescent, Suite 890 Broomfield, CO 80021 (303) 443-7500
Contact Person:	William Sandul
Date Prepared:	March 29, 2010

Device Identification

Proprietary Name:	Lanx Posterior Cervicothoracic Spinal Fixation System (PCFS)
Common Name:	Spinal Fixation System
Classification:	KWP - 21 CFR 888.3050 - Spinal Interlaminal Fixation Orthosis

Predicate Device Information

K092656	Lanx PCFS	Lanx, Inc.

Intended Use / Indications for Use

When intended to promote fusion of the occipito-cervico-thoracic region of the spine (occiput-T3) in skeletally mature patients, the Lanx Posterior Cervicothoracic Spinal Fixation System is indicated for the following:

- Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Trauma/Fracture/Dislocation
- Atlanto-Axial Fracture with Instability
- Occipito-Cervical Dislocation
- Failed Previous Fusion
- Tumor

The use of occipital bone screws is limited to placement in the occiput only.

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

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Device Description and Technological Characteristics

The purpose of this 510(k) submission is to add a head-to-head cross connector and additional longitudinal rods and polyaxial pedicle screws. The modified system has the same intended use and fundamental scientific technology as the previously-cleared system.

Both the modified and predicate Lanx Posterior Cervicothoracic Spinal Fixation System consist of various screws, hooks, plates, rods, connectors, etc. that are used to build a construct to provide supplemental stabilization of spinal segments to support fusion. The system components can be assembled in a variety of configurations, with the anchors and connectors rigidly locked to the rod, allowing the surgeon to tailor the construct to the particular needs of the patient.

Both the modified and predicate Lanx Posterior Cervicothoracic Spinal Fixation System implants are fabricated from medical grade titanium alloy per ASTM F136. The modified Lanx Posterior Cervicothoracic Spinal Fixation System implants are manufactured using the same manufacturing processes, and are passivated and anodized in the same manner as the implants in the predicate Lanx Posterior Cervicothoracic Spinal Fixation System.

Performance Data

Performance testing was conducted to characterize the modified Lanx Posterior Cervicothoracic Spinal Fixation System. Static and dynamic axial compression bending and static and dynamic torsion testing were performed in accordance ASTM F1717 on the modified and predicate systems, and the results compared. Also, axial grip and cantilever bending testing was performed in accordance with ASTM F1798 on the modified and predicate system, and the results compared. The modified device functioned as intended and the observed test results demonstrate substantial equivalence to a predicate device.

Substantial Equivalence

The modified Lanx Posterior Cervicothoracic Spinal Fixation System has the same intended use, indications, technological characteristics, and principles of operation as the predicate system. The modifications to the Lanx Posterior Cervicothoracic Spinal Fixation System do not raise new issues of safety or effectiveness. Also, mechanical testing demonstrated comparable mechanical properties to the predicate device. Thus, the modified Lanx Posterior Cervicothoracic Spinal Fixation System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Lanx, Inc.
% Mr. William H. Sandul
Director, Product Development
390 Interlocken Crescent, Suite 890
Broomfield, Colorado 80021

NOV 15 2010

Re: K100888
Trade/Device Name: Lanx Posterior Cervicothoracic Spinal Fixation System (PCFS)
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: October 19, 2010
Received: October 20, 2010

Dear Mr. Sandul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buehler for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

NOV 15 2010

510(k) Number (if known): K100889

Device Name: Lanx Posterior Cervicothoracic Spinal Fixation System

Indications for Use:

When intended to promote fusion of the occipito-cervico-thoracic region of the spine (occiput-T3) in skeletally mature patients, the Lanx Posterior Cervicothoracic Spinal Fixation System is indicated for the following:

- Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
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Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100888